

## **Senate Bill No. 225**

### **CHAPTER 352**

An act to amend Sections 117630, 117904, 117943, 117945, 117975, 118032, 118040, 118345, and 118275 of the Health and Safety Code, relating to medical waste, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 28, 2015. Filed with  
Secretary of State September 28, 2015.]

#### **LEGISLATIVE COUNSEL'S DIGEST**

SB 225, Wieckowski. Medical waste.

(1) Under existing law, the Medical Waste Management Act, the State Department of Public Health regulates the disposal of medical waste. The act requires specified biohazard materials to be disposed of in biohazard bags and requires specified treatment for medical waste. Transportation, storage, treatment, or disposal of medical waste in a manner not authorized by the act is a crime. Existing law defines specified terms for purposes of the Medical Waste Management Act, including "biohazard bag." Existing law defines a biohazard bag to mean a film bag that is impervious to moisture. Existing law requires the film bags that are used for transport to be marked and certified by the manufacturer as having passed specified tests prescribed for tear resistance and for impact resistance.

This bill would revise the definition of "biohazard bag" and would limit the application of the requirement that film bags used for transport be marked and certified by the manufacturer as having passed specified tests only to those film bags that are used for transport from the generator's facility onto roadways and into commerce to a treatment and disposal facility. The bill would revise the requirements for biohazard bags that are used to collect medical waste within a facility, as specified.

(2) Existing law requires a hazardous waste transporter or generator transporting medical waste to maintain a completed shipping document in compliance with the United States Department of Transportation and a tracking document if the waste is transported to a facility other than the final medical waste treatment facility.

This bill would instead require a hazardous waste transporter that transports medical waste to maintain a tracking document in compliance with specified requirements for purposes of tracking medical waste from the point when the waste leaves the generator facility until the waste receives final treatment. The bill would also require the tracking document to be maintained only by hazardous waste transporters, and not by generators transporting waste. The bill would also make conforming changes.

(3) This bill would declare that it is to take effect immediately as an urgency statute.

*The people of the State of California do enact as follows:*

SECTION 1. Section 117630 of the Health and Safety Code is amended to read:

117630. (a) “Biohazard bag” means a disposable film bag used to contain medical waste. Notwithstanding subdivision (b) of Section 117605, the film bags that are used to line the United States Department of Transportation (USDOT)-approved shipping containers for transport from the generator’s facility onto roadways and into commerce to a treatment and disposal facility shall be marked and certified by the manufacturer as having passed the tests prescribed for tear resistance in the American Society for Testing Materials (ASTM) D1922, “Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method” and for impact resistance in ASTM D1709, “Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method,” as those documents were published on January 1, 2014. The film bag shall meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both parallel and perpendicular planes with respect to the length of the bag.

(b) The biohazard bag that is used to collect medical waste within a facility shall be manufacturer certified to meet the ASTM D1709 dart drop test, provided that when the bag is prepared for transport offsite, it is placed into a USDOT-approved container lined with a biohazard bag that is ASTM D1709 and ASTM D1922 certified.

(c) The color of the bag shall be red, except when yellow bags are used to further segregate trace chemotherapy waste and white bags are used to further segregate pathology waste. The biohazard bag shall be marked with the international biohazard symbol and may be labeled by reference as authorized by the USDOT.

SEC. 2. Section 117904 of the Health and Safety Code is amended to read:

117904. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated sharps waste, which, after collection, shall be transported and treated as medical waste.

(b) A consolidation location approved pursuant to this section shall be known as a “home-generated sharps consolidation point.”

(c) A home-generated sharps consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275), to the permit or registration requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated sharps waste pursuant to this section.

(d) A home-generated sharps consolidation point shall comply with all of the following requirements:

- (1) All sharps waste shall be placed in sharps containers.
- (2) Sharps containers ready for disposal shall not be held for more than seven days without the written approval of the enforcement agency.
- (e) An operator of a home-generated sharps consolidation point approved pursuant to this section shall not be considered the generator of that waste, but shall be listed on the tracking documents in compliance with the United States Postal Service requirements for waste shipped through mail back and on the tracking documents as required by the department.
- (f) The medical waste treatment facility which treats the sharps waste subject to this section shall maintain the tracking document required by Sections 118040 and 118165 with regard to that sharps waste.

SEC. 3. Section 117943 of the Health and Safety Code is amended to read:

117943. (a) A medical waste generator required to register pursuant to this chapter shall maintain for a minimum of three years individual treatment operating records, and if applicable, the tracking document for all untreated medical waste shipped offsite for treatment, and shall report or submit to the enforcement agency, upon request, all of the following:

- (1) Treatment operating records. Operating records shall be maintained in written or electronic form.
- (2) An emergency action plan complying with regulations adopted by the department.
- (3) Tracking documents or electronically archived tracking documents maintained by the facility and medical waste hauler of all untreated medical waste shipped offsite for treatment.

(b) Documentation shall be made available to the enforcement agency onsite.

SEC. 4. Section 117945 of the Health and Safety Code is amended to read:

117945. (a) Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

- (1) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.
- (2) Records required by the United States Postal Service of any medical waste shipped offsite for treatment and disposal. The small quantity generator shall maintain, or have available electronically at the facility or from the medical waste hauler or common carrier, these records, for not less than three years.

(b) Documentation shall be made available to the enforcement agency onsite.

SEC. 5. Section 117975 of the Health and Safety Code is amended to read:

117975. (a) A large quantity medical waste generator required to register pursuant to this chapter shall maintain for a minimum of two years individual treatment records and the tracking document for all untreated medical waste

shipped offsite for treatment. The generator shall report or submit to the enforcement agency, upon request, all of the following:

(1) Treatment operating records. Operating records shall be maintained in written or electronic form.

(2) An emergency action plan in accordance with regulations adopted by the department.

(3) Tracking documents or electronically archived tracking documents maintained by the facility or medical waste hauler of all untreated medical wastes shipped offsite for treatment.

(b) Documentation shall be made available to the enforcement agency onsite as soon as feasible, but no more than two business days following the request.

SEC. 6. Section 118032 of the Health and Safety Code is amended to read:

118032. A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

(a) The generator or parent organization has on file one of the following:

(1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117925), a medical waste management plan prepared pursuant to Section 117935.

(2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117925), the information document maintained pursuant to subdivision (a) of Section 117945.

(3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the tracking document, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the tracking document, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies

between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

(A) The name of the person transporting the pharmaceutical waste.

(B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate pharmaceutical waste container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.

(C) The date that the pharmaceutical waste was returned.

(2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the pharmaceutical waste.

(3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

SEC. 7. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter transporting medical waste shall maintain a completed tracking document in compliance with subdivision (b) for the purpose of tracking the medical waste from the point when the waste leaves the generator facility until it receives final treatment. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document. The transporter transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 117946 or 117976.

(2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) A hazardous waste transporter transporting medical waste in a vehicle shall have the tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

SEC. 8. Section 118275 of the Health and Safety Code is amended to read:

118275. (a) To containerize or store medical waste, at the point of generation and while collected in that room, a person shall do all of the following:

(1) Medical waste, as defined in Section 117690, shall be contained separately from other waste at the point of origin in the producing facility. Sharps containers may be placed in biohazard bags or in containers with biohazard bags.

(2) Biohazardous waste, as defined in paragraph (1) of subdivision (b) of Section 117690, shall be placed in a biohazard bag and labeled in compliance with Section 117630.

(3) Sharps waste, as defined in paragraph (4) of subdivision (b) of Section 117690, including sharps and pharmaceutical waste containerized pursuant to paragraph (7), shall be contained in a United States Food and Drug Administration (USFDA) approved sharps container that meets USFDA labeling requirements and is handled pursuant to Section 118285.

(4) Trace chemotherapy waste, as defined in paragraph (5) of subdivision (b) of Section 117690, shall be segregated for storage, and, when placed in a secondary container, that container shall be labeled with the words "Chemotherapy Waste," "CHEMO," or other label approved by the department on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the biohazardous waste pursuant to Section 118222. Sharps waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, shall be placed in sharps containers labeled in accordance with the industry standard with the words "Chemotherapy Waste," "CHEMO," or other label approved by the

department, and shall be segregated to ensure treatment of the sharps waste pursuant to Section 118222.

(5) Pathology waste, as defined in paragraph (2) of subdivision (b) of Section 117690, shall be segregated for storage and, when placed in a secondary container, that container shall be labeled with the words “Pathology Waste,” “PATH,” or other label approved by the department on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the waste pursuant to Section 118222.

(6) Pharmaceutical waste, as defined in paragraph (3) of subdivision (b) of Section 117690, shall be segregated for storage in accordance with the facility’s medical waste management plan. When this waste is prepared for shipment offsite for treatment, it shall be properly containerized for shipment in compliance with United States Department of Transportation and the United States Drug Enforcement Administration (DEA) requirements.

(A) Pharmaceutical wastes classified by the DEA as “controlled substances” shall be disposed of in compliance with DEA requirements.

(B) Nonradioactive pharmaceutical wastes that are not subject to the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended, and that are regulated as medical waste are placed in a container or secondary container labeled with the words “HIGH HEAT” or “INCINERATION ONLY,” or with another label approved by the department, on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the biohazardous waste pursuant to Section 118222.

(7) A person may consolidate into a common container, which may be reusable, sharps waste, as defined in paragraph (4) of subdivision (b) of Section 117690, and pharmaceutical wastes, as defined in paragraph (3) of subdivision (b) of Section 117690, provided that both of the following apply:

(A) The consolidated waste is treated by incineration or alternative treatment technologies approved to treat that waste pursuant to paragraph (1) or (3) of subdivision (a) of Section 118215 prior to disposal. That alternative treatment shall render the waste unrecoverable and nonhazardous.

(B) The container meets the requirements of Section 118285. The container shall be labeled with the biohazardous waste symbol and the words “HIGH HEAT” or “INCINERATION ONLY,” or with another label approved by the department, on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the waste pursuant to this subdivision.

(b) To containerize medical waste being held for shipment offsite for treatment, the waste shall be labeled, as outlined in subdivision (a), on the lid and sides of the container.

(c) When medical waste is containerized pursuant to subdivisions (a) and (b) there is no requirement to label the containers with the date that the waste started to accumulate.

SEC. 9. Section 118345 of the Health and Safety Code is amended to read:

118345. (a) Any person who intentionally makes any false statement or representation in any application, label, tracking document, record, report,

permit, registration, or other document filed, maintained, or used for purposes of compliance with this part that materially affects the health and safety of the public is liable for a civil penalty of not more than ten thousand dollars (\$10,000) for each separate violation or, for continuing violations, for each day that the violation continues.

(b) Any person who fails to register or fails to obtain a medical waste permit in violation of this part, or otherwise violates any provision of this part, any order issued pursuant to Section 118330, or any regulation adopted pursuant to this part, is liable for a civil penalty of not more than ten thousand dollars (\$10,000) for each violation of a separate provision of this part or, for continuing violations, for each day that the violation continues.

SEC. 10. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that necessary and technical changes to the laws governing the handling and disposal of medical waste are implemented as soon as possible, it is necessary that this act take effect immediately.